3M

EC DECLARATION OF CONFORMITY

93/42/EEC on Medical Devices (MDD) Annex II excluding (4).

Manufacturer:

3M ESPE Dental Products
2510 Conway Avenue
St. Paul, Minnesota 55144-1000
USA

EC Certificate No: G1 16 05 45735 030
Valid until: 2021-12-03

GMDN CODE: 34976 Dental Crown,
preformed, temporary

Manufacturing Facility:

3M ESPE Dental Products
2111 McGaw Avenue
Irvine, California 92614
USA

Product Family: Preformed Crowns

Product: Protemp™ Crowns
Temporization Material

EC Product Class: IIa
Rule: 7
Per Annex IX of the Medical Device Directive

Declaration of Conformity

3M ESPE Dental Products has sole responsibility and declares that the devices listed on the attached Device Schedule conform to the relevant provisions of the EC Council Directive 93/42/EEC dated 14 June 1993 and are in accordance with ISO 13485:2016, Medical devices - Quality management systems – Requirements for regulatory purposes, as implemented by the European Union's Medical Devices Regulations and verified by TüV SüD Product Service GMBH, Ridlerstrasse 65, 80339 Munich Germany, CE 0123.

3M ESPE Dental Products has appointed 3M Deutschland GmbH as our EU Authorized Representative.
3M Deutschland GmbH
Carl-Schurz-Strasse 1
41453 Neuss, Germany

Suzanne Leung
Suzanne Leung

Manager
3M ESPE
Regulatory Affairs
Title

St. Paul, MN USA
Location

30 Aug 2019
Date

EC DECLARATION OF CONFORMITY

Product Family: **Preformed Crowns**
Device Description: Non-Sterile Dental Crown
EC Product Class (Per Annex IX Rules): Class: IIa   Rule: 7
Product:
♦ Protemp™ Crowns

Kits	Description
50600	Protemp Crown Temporization Material - Introductory Kit • 42 Temporary Crowns ○ 6 - Molar Upper Large and Upper Small each ○ 6 - Molar Lower Large and Lower Small each ○ 4 - Bicuspid Upper Large and Upper Small each ○ 4 - Bicuspid Lower ○ 3 - Cuspid Large ○ 3 - Cuspid Small • Sizing Tools (2 bags of 10)
50600TK	Protemp Crown Temporization Material – Trial Kit • 16 Temporary Crowns ○ 3 - Molar Upper Large and Upper Small each ○ 2 - Molar Lower Large and Lower Small each ○ 2 - Bicuspid Upper Large and Upper Small each ○ 2 - Bicuspid Lower • Sizing Tools (1 bag of 10)
50600SAM	Protemp Crown Temporization Material – Promotional Kit • 50600 Kit • 50613 Refill
50600SP	Protemp Crown Temporization Material – Sample Pack • 2 Temporary Crowns – Molar Upper Small • 1 Sizing tool
Refills	**Description**
50610	Protemp Crown Temporization Material - Molar Upper Large • 5 Temporary Crowns – Molar Upper Large • 2 Sizing Tools
50611	Protemp Crown Temporization Material - Molar Upper Small • 5 Temporary Crowns – Molar Upper Small • 2 Sizing Tools
50612	Protemp Crown Temporization Material - Molar Lower Large • 5 Temporary Crowns – Molar Lower Large • 2 Sizing Tools
50613	Protemp Crown Temporization Material - Molar Lower Small • 5 Temporary Crowns – Molar Lower Small • 2 Sizing Tools
50614	Protemp Crown Temporization Material – Bicuspid Upper Large • 5 Temporary Crowns – Bicuspid Upper Large • 2 Sizing Tools
50615	Protemp Crown Temporization Material – Bicuspid Upper Small • 5 Temporary Crowns – Bicuspid Upper Small • 2 Sizing Tools
50616	Protemp Crown Temporization Material – Bicuspid Lower • 5 Temporary Crowns – Bicuspid Lower • 2 Sizing Tools
50617	Protemp Crown Temporization Material – Cuspid Large • 5 Temporary Crowns – Cuspid Large • 2 Sizing Tools
50618	Protemp Crown Temporization Material – Cuspid Small • 5 Temporary Crowns – Cuspid Small • 2 Sizing Tools